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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/729,343	10/16/1996	DOSUK D. LEE		3866

7590

06/18/2002

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EXAMINER

WARE, TODD

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/18/2002

36

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/729,343

Applicant(s)

LEE ET AL.

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-3,5,7,9-16,22,23,25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7,9-16,22,23,25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Receipt of change of address filed 10-14-01 and revocation and new power of attorney filed 4-18-02 and CPA request filed 10-19-01 is acknowledged. Claims 1-3, 5, 7, 9-16, 22-23, 25-26 are pending.

Continued Prosecution Application

1. The request filed on 10-19-01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/729,343 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3, 5, 7, 9-16, 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1, 3, 7, 9, 10-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

5. Recitation of "the PCA calcium phosphate have a calcium to phosphate ratio (CA:P) in the range of 1.2-1.68" is indefinite since it is unclear what units the ratio is in and whether the ratio is intended to encompass the instance where calcium is 1.2 when phosphorous is 1.68 or 1.2 moles calcium to 1 mole phosphorous to 1.68 moles calcium to every mole phosphorous. For purposes of examination, this limitation is understood

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to mean that the range is in moles and encompasses 1.2 moles calcium to 1 mole phosphorous to 1.68 moles calcium to every mole phosphorous.

6. Regarding claims 1, 3, 7, 9, 10-16, the phrase "similar" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "similar"), thereby rendering the scope of the claim(s) unascertainable.

7. Regarding claims 2, 5, 10-16, 22-23, "identifying a bone site suitable for receiving an implant" is indefinite since the claims do not set for the steps required for identification of the site nor who/where identifies the site nor what the requirements of the site are.

8. Regarding claims 2, 5, 10-16, 22-23, and 25 the phrase "associated with an endothermic reaction" is indefinite since the claims do not specify the manner in which the process is "associated" with the reaction. Does the process result from an endothermic reaction? Does it react with something to cause an endothermic reaction?

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3, 5, 7, 9-16, 22-23, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Simkiss (WO 94/02412; hereafter '412).

'412 discloses injectable amorphous calcium phosphate that hardens to form bone in vivo. It is the position of the examiner that the instant ratio of calcium to phosphorous is disclosed in '412. '412 discloses hydroxyapatite as $\text{Ca}_5(\text{OH})\text{PO}_4)_3$. The molar ratio of Ca to P is 1.67. '412 goes on to disclose negligible amounts of magnesium in the composition (as low as 0.001 moles for 1 mole calcium). Thus, the ratio of Ca to P is within the instant range. This also applies to tricalcium phosphate, $\text{Ca}_3(\text{PO}_4)_2$. Applicant has previously argued (in response to a 35 U.S.C. 103(a) rejection) that '412 doesn't disclose that the composition is resorbable. '412 discloses compositions comprising hydroxyapatite or tricalcium phosphate having magnesium and tricalcium phosphate is known to be resorbable. Furthermore, being that the Patent Office is not capable of manufacture products and testing them, the burden is shifted to the applicant to demonstrate that that these compositions do not have the claimed functional limitations. This also applies to arguments regarding the endothermic reaction limitations. The instant claims (those dependant on and including claim 2) require an acidic second calcium phosphate. Dependant claims state that this is PCA calcium phosphate. Thus, '412 also anticipates these claims since this limitation only requires PCA calcium phosphate in the composition of the instant methods.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-3, 5, 7, 9-16, 22-23, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simkiss (WO 94/02412; hereafter '412).

'412 teaches injectable amorphous calcium phosphate that hardens to form bone in vivo. It is the position of the examiner that the instant ratio of calcium to phosphorous is disclosed in '412. '412 discloses hydroxyapatite as $\text{Ca}_5(\text{OH})\text{PO}_4)_3$. The molar ratio of Ca to P is 1.67. '412 goes on to disclose negligible amounts of magnesium in the composition (as low as 0.001 moles for 1 mole calcium). Thus, the ratio of Ca to P is within the instant range. This also applies to tricalcium phosphate, $\text{Ca}_3(\text{PO}_4)_2$. Applicant has previously argued (in response to a 35 U.S.C. 103(a) rejection) that '412 doesn't disclose that the composition is resorbable. '412 discloses compositions comprising hydroxyapatite or tricalcium phosphate having magnesium and tricalcium phosphate is known to be resorbable. Furthermore, being that the Patent Office is not capable of manufacture products and testing them, the burden is shifted to the applicant to

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demonstrate that that these compositions do not have the claimed functional limitations. This also applies to arguments regarding the endothermic reaction limitations. The instant claims (those dependant on and including claim 2) require an acidic second calcium phosphate. Dependant claims state that this is PCA calcium phosphate. Thus, '412 also anticipates these claims since this limitation only requires PCA calcium phosphate in the composition of the instant methods.

14. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simkiss (WO 94/02412; hereafter '412) in view of Gerhart et al (4,843,112; hereafter '112).

'412 is relied upon for all that it teaches as stated previously. '412 does not teach the limitation where the composition is in a kit .

'112 teaches ceramic bone cement kits comprising tricalcium phosphate or hydroxyapatite.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to provide a kit for the composition of '412 provides a convenient package for surgical applications.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-3, 5, 7, 9-16, 22-23, and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-27 of U.S. Patent No. 6,287,341. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant methods disclose the composition of '341.

17. Claims 1-3, 5, 7, 9-16, and 22-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-27 of U.S. Patent No. 6,287,341; claims 1-14 of U.S. Patent No. 6,214,368; claims 1-2 of U.S. Patent No. 6,132,463; claims 1-21 of U.S. Patent No. 6,027,742; claims 1-9 of U.S. Patent No. 6,331,312. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant methods are either the genus of a claimed species or disclose a claimed composition.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone

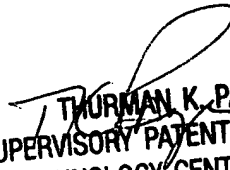
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numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw

June 14, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600